UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Monday, April 20, 2015

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 67603-RE
Product Name: Sanitizer #1
DP Barcode: D424258
Decision No: 497099
Action Code: A540
PC Code: 069105

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
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To: Velma Noble, PM 31/ John C. Cowden
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Sherwin-Williams Diversified Brands

FORMULATION FROM LABEL:

PC Code	Active Ingredient(s):	% by wt.
069105	Alkyl dimethyl benzyl ammonium chloride	0.52
	Other Ingredient(s):	99.48
	Total:	100.00

I) Background Information: Sherwin-Williams has submitted an application for a new end-use product, "Sanitizer #1", to be used as an antimicrobial paint. The registrant cites the following studies in support of their registration.

Study	MRID Number
Acute Oral Toxicity	49420303
Acute Dermal Toxicity	49420304
Acute Inhalation Toxicity	49420305
Primary Eye Irritation	49420306
Primary Skin Irritation	49420307
Dermal Sensitization	49420308

II) Findings: The studies all state that they were conducted using "Sanitizer #1". However, where the label and CSF of Sanitizer #1 state that this product contains only one active ingredient, the

1) Each of the six submitted studies is acceptable.

2) The registrants had the laboratory conduct the dermal sensitization study using the Buehler Method. EPA's Pesticide Program has been using the local lymph node assay (LLNA) for assessment of dermal sensitization potential of technical grade active ingredients. Now, we are expanding the use of this test to end-use products. In addition, we are adopting the reduced or limit-dose LLNA (or rLLNA) radio-labeled assay, which will further reduce the number of animals used in laboratory testing. EPA prefers the LLNA because it incorporates the principles of the 3 R's of animal testing: replacement, refinement and reduction.

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49420303	IV	Acceptable
Acute Dermal Toxicity	49420304	IV	Acceptable
Acute Inhalation Toxicity	49420305	IV	Acceptable
Primary Eye Irritation	49420306	III	Acceptable
Primary Skin Irritation	49420307	III	Acceptable
Dermal Sensitization	49420308	Nonsensitizer	Acceptable

III) Precautionary Labeling:

Product Reg. No.: 67603-RE

Product Name: Sanitizer #1

Signal Word: Caution

Hazards to Humans and Domestic Animals:

"Causes moderate eye irritation. Avoid contact with skin eyes or clothing. Wash thoroughly with soap and water after handling, before eating, drinking

First Aid:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment advice.

If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: 31 **Reviewer:** I. Blackwell **Testing Laboratory:** Product Safety Labs

MRID No.: 49420303 **Study Completion Date:** 5/16/2013

Lab Study No.: 33695

Authors: Aija McKenzie, BA, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Sanitizer #1, Batch #2011-130:79; "white liquid"

Species: Sprague-Dawley derived albino rats

Weight: 172-187 g **Age:** 10 weeks

Source: Harlan Laboratories, Inc.

Conclusion:

1. LD_{50} (mg/kg):

Males > 5,000

Females > 5,000

Combined > 5,000

2. The estimated LD_{50} is greater than 5,000 mg/kg b.w.

3. **Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviations from §81-1): None

Method: Up and Down Procedure

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	---	0/3	---

Observations: Active and healthy.

Gross Necropsy: The lab reported no gross abnormalities.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 31 **Reviewer:** I. Blackwell
MRID No.: 49420304 **Study Completion Date:** 2/18/2013
Lab Study No.: 33696

Testing Laboratory: Product Safety Labs
Author: Aija McKenzie, BA, LATG
Quality Assurance (40 CFR §160.12): Included

Test Material: Sanitizer #1, Batch #2011-130:79; "white liquid"

Species: Sprague-Dawley derived albino rats
Weight: Males= 239-266 g **Age:** 8-9 weeks
Females= 176-195 g
Source: Harlan Laboratories, Inc.

Summary:

1. **LD_{50} (mg/kg):**

Males	> 5,000
Females	> 5,000
Combined	> 5,000

2. **The estimated LD_{50} is greater than 5,000 mg/kg.**

3. **Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviation From §81-2): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5,000	0/5	0/5	0/10

Observations: Erythema, eschar or desquamation at dose site; red ocular discharge

Gross Necropsy Findings: The lab reported no gross abnormalities.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 31
MRID No.: 49420305

Reviewer: I. Blackwell
Study Completion Date: 5/3/2013
Lab Study No.: 33697

Testing Laboratory: Product Safety Labs
Author: Aiha McKenzie, BA, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Sanitizer #1, Batch #2011-130:79; "white liquid"

Concentration: 2.08 mg/L (gravimetric)

Species: Sprague-Dawley derived albino rats
Weight: Males= 280 -290 g Females= 187-230 g
Age: 10-11 weeks
Source: Harlan Laboratories, Inc.

Summary:

1. **LC_{50} (mg/L)** **Males** > 2.08
   Females > 2.08
   Combined > 2.08
2. **The estimated LC_{50} is greater than 2.08 mg/L of air.**
3. **MMAD:** 2.5 **µm**
4. **Toxicity Category:** IV **Classification:** Acceptable

Procedure (Deviation From §81-3): None

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.08 mg/L	0/5	0/5	0/10

Chamber Atmosphere		
Dose Level	MMAD	GSD
2.08 mg/L	2.5 μm	2.205 μm

Chamber Environment	
Chamber Volume	28 liters
Airflow	
Temperature	° C
Relative Humidity	%

Clinical Observations: Moist rales, irregular respiration.

Gross Necropsy Findings: No gross abnormalities.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 31
MRID No.: 49420306

Reviewer: I. Blackwell
Study Completion Date: 2/18/2013
Lab Study No.: 33698

Testing Laboratory: Product Safety Laboratories
Author(s): Aija McKenzie, BS, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Sanitizer #1, Batch #2011-130:79; "white liquid"
Dosage: 0.1 mL

Species: New Zealand albino rabbit
Weight: Not reported
Source: Robinson Services

Sex: 3 females
Age: "young adult"

Summary:

1. **Toxicity Category:** III

2. **Classification:** Acceptable

Procedure (Deviations From §81-4): none

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	1/3	0/3	0/3	0/3	---	---	---
Iritis	0/3	0/3	0/3	0/3	0/3	---	---	---
Conjunctivae								
Redness	3/3	3/3	1/3	0/3	0/3	---	---	---
Chemosis	2/3	1/3	0/3	0/3	0/3	---	---	---
Discharge	3/3	3/3	1/3	0/3	0/3	---	---	---

- - - = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 31
MRID No.: 49420307

Reviewer: I. Blackwell
Study Completion Date: 5/30/2013
Lab Study No.: 36004

Testing Laboratory: Product Safety Laboratories
Study Director: Aija McKenzie, BA, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Sanitizer #1, Batch #2011-130:79; "white liquid"
Dosage: 0.5 mL

Species: New Zealand Albino rabbit
Weight: Not reported
Source: Robinson Services, Inc.

Age: "young adult"

Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

Procedure (Deviations From §81-5): None

Results: One hour after dosing, 3/3 treated animals had very slight erythema, and 2/3 had very slight edema. Twenty-four, forty-eight and seventy-two hours after dosing, 2/3 had well-defined erythema, 1/3 very slight erythema, and 2/3 very slight edema. On Day 7 of the study, only desquamation was reported in the animals.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 31 **Reviewer:** I. Blackwell
MRID No.: 49420308 **Study Completion Date:** 5/3/2013
Lab Study No.: 33700

Testing Laboratory: Product Safety Labs
Author: Aija McKenzie, BA, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Sanitizer #1, Batch #2011-130:79; "white liquid"
Positive Control Material: α-HexylCinnamAldehyde (HCA)

Species: Hartley albino guinea pig
Weight: 380 - 479 g **Age:** "young adult"
Source: Elm Hill Breeding Labs

Method: Buehler Method

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification:** Acceptable

Procedure (Deviation From §81-6): None

Procedure:
Buehler Method

Induction: Twenty males were dosed with 0.4 mL of 100% (neat) test material using an occlusive 25 mm Hill Top Chamber. After 6 hours, the patches and test material were removed and the exposure site cleansed with distilled water. This procedure was repeated once a week for the following two weeks (Days 7 and 14 of the study), for a total of three induction exposures.

Challenge: Twenty-seven days after the first induction exposure, the test material-induced animals were challenged using the same dosing procedure with 0.4 mL of a 75% solution.

Results:

Challenge: Twenty-four hours after challenge, 2/20 test material-treated animals had very faint erythema (0.5). All irritation cleared by the 48 hour assessment.

Naïve control: Twenty four hours after challenge, 2/10 had very faint erythema.

Positive control: Twenty-four hours after challenge, 3/10 displayed faint (1.0) erythema.